REMARKS

Claims 1-59 are pending in the application. Claims 13, 29-54 and 57-59 have been cancelled. Claims 1-2 and 24 have been amended. Upon entry of the present Amendment, claims 1-12, 14-28, and 55-56 will be pending.

Claims 1-2 and 24 have been amended to specify that the antibodies encompassed by the claimed methods bind to human DEC-205 or mouse DEC-205. Support for these amendments can be found at least, for example at pages 46-47, paragraphs 142-143.

No new matter has been added. The amendments presented herein should in no way be construed as an acquiescence to any of the Examiner's rejections and were made solely in the interest of expediting prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Finally, Applicants respectfully note that the present application is now being handled by the new attorneys of record.

Information Disclosure Statements

At page 3, paragraph 7 of the Office Action that Examiner states the Information Disclosure Statements filed on 3/12/04 and 11/20/06 have not been considered because the cited references lack titles as required under 37 C.F.R. § 1.98(b)(5).

Responsive to the Examiner's request, Applicants submit herewith a comprehensive Information Disclosure Statement, and accompanying PTO/SB/08 Form and respectfully request that the Examiner consider and initial each of the cited references.

Elections/Restrictions

Applicants hereby confirm the election of Group I for continued examination (drawn to methods of antigen presentation).

Applicants further confirm the species election of a tumor cell. As acknowledged by the Examiner, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141.

Objection to Claim 46

The Examiner has objected to claim 46 as depending from a non-elected invention. To expedite prosecution, claim 46 has been cancelled, thereby rendering this objection moot. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this objection.

Amendment to the Specification

At page 2, paragraph 5 of the Office Action, the Examiner requires that Applicants update the status of all U.S. applications disclosed in the specification, *i.e.*, page 47.

Responsive to this requirement, Applicants have amended the specification at page 47 to specify that U.S. serial Number 08/381,528 has been "abandoned." Accordingly, this rejection should now be moot.

Oath/Declaration

The Examiner has indicated that the oath or declaration is defective because non-initialed and non-dated changes have been made to Inventor Nussenzweig's citizenship.

In response, Applicants submit herewith a supplemental declaration executed by Inventor Nussenzweig in compliance with 37 C.F.R. 1.67(a). Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this objection.

Rejection of Claims 1-12, 14-28, 46 and 55-56 Under 35 U.S.C. § 112

Claims 1-12, 14-28, 46 and 55-56 are rejected as failing to comply with the written description requirement. In particular, the Examiner asserts that the specification only provides the amino acid sequences encoding full length murine and full length human DEC-205 and does not provide adequate written description for methods which encompass an anti-DEC antibody which binds DEC-205 from any mammalian species or mutants/variants of the disclosed amino acid species.

Applicants respectfully traverse this rejection. However, to expedite prosecution, Applicants have amended claims 1-2 and 24 to specify that the antibodies encompassed by the claimed methods bind to human DEC-205 or mouse DEC-205, thereby obviating this rejection. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Rejection of Claims 1-12, 14-28, 46 and 55-56 Under 35 U.S.C. § 112

Claims 1-12, 14-28, 46 and 55-56 are rejected as failing to comply with the written description requirement. In particular, the Examiner asserts that while the specification provides several examples of dendritic cell maturation factors, it does not provide support for variants and mutants of dendritic cell maturation factors. Additionally, the Examiner is of the opinion that "the claims encompass a vast collection of unknown molecules with the functional activity recited in the claims wherein the identity of such molecules is unknown and structurally unpredictable (mimetics, nonprotein molecules, *etc*)."

Applicants respectfully traverse this rejection. In order to meet the written description requirement of the first paragraph of 35 U.S.C. § 112, it is not necessary that a patent specification describe *each* and *every* specific member of a genus recited in a claim. "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A 'representative number of species' means that the species which are adequately described are representative of the entire genus." See MPEP § 2163.05 and *The Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997). In the present case, Applicants' specification describes numerous representative species of dendritic cell maturation factors to support the genus of dendritic cell maturation factors that is encompassed by the presently claimed methods (see, for example, page 13, paragraph 39 of the specification as originally filed).

Moreover, importantly, it is firmly established that a patent specification need not describe information that was well known in the art to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Indeed, the written description requirement varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. In *Capon v. Eshhar,* 418 F.3d 1349, 1357 (Fed. Cir. 2005) (hereinafter "*Capon*"), the Federal Circuit explained that "[p]recedent illustrates that the determination of what is needed to support generic claims to biological subject matter depends on a *variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter*. Id. at 1359 (emphasis added)." Accordingly, if the art is mature, less written description is required.

Specifically, in *Capon*, the claims at issue were drawn to DNA molecules encoding chimeric cell-surface receptor proteins made up of two portions having art-recognized (known) amino acid and nucleotide sequences. The Federal Circuit vacated the Board of Patent Appeals and Interference's decision invalidating these claims for lack of written description on the grounds that the sequences of the claimed chimeric DNA molecules were not explicitly disclosed in specification. The Federal Circuit held that the written description requirement did not require recitation of the nucleotide sequence of the claimed DNA in the specification because the sequence was already known in the field.

The facts of *Capon* parallel those of the present application. Similar to *Capon*, Applicants should not be required to describe each and every dendritic cell maturation factor in the specification, since such factors were clearly well known in the art at the time of filing the present application. For example, as evidenced by column 4, paragraph 1, of U.S. Patent No.: 6,602,709 (filed February 19, 1999; enclosed herewith as Appendix A), numerous dendritic cell maturation factors were known in the art prior to the present invention.

Accordingly, in view of the numerous representative species described in Applicant's specification and, importantly, the fact that dendritic cell maturation factors were well known in the art at the time of filing, the present application provides more than adequate written description for the claimed genus of dendritic cell maturation factors encompassed by the presently claimed methods. Accordingly, the requirement of 35 U.S.C. § 112, first paragraph for written description has been satisfied and Applicants respectfully request reconsideration and withdrawal of this rejection.

Priority and Rejection of Claims 1, 3-7, 10-11, 14-17, 19, 21-25, 46 and 55 Under 35 U.S.C. § 102(b)

As indicated at page 6, paragraph 11 of the present Office Action, the Examiner asserts that the pending claims are not entitled to the benefit of priority to parent applications, *i.e.*, U.S. Patent Application No. 09/925,284 (filed August 9, 2001), U.S. Patent Application No. 09/586,704 (filed June 5, 2000), PCT/US96/01383 (January 31, 1996) and U.S. Patent Application No. 08/381,528 (filed January 31, 1995). Accordingly, the Examiner has rejected all of the pending claims as lacking novelty under 35 U.S.C. § 102(b) in view of Bonifaz *et al.*, (*J Exp Med.*, 196(12):1627-38 (2002 Dec 16)). The Examiner relies on Bonifaz *et al.* for teaching *in vivo* subcutaneous administration to a mammal of a non-

replicating antigen/anti-DEC-205 monoclonal antibody covalent conjugate and a dendritic cell maturation factor (agonist anti-CD40 antibody), wherein the dendritic cells are contacted with the aforementioned reagents *in vivo*.

Applicants respectfully traverse this rejection and submit that Bonifaz *et al.* is not available as a prior art reference against the present application. It is well established that the requirement for claiming priority under 35 U.S.C. §120 is that the specification of the priority application satisfy the requirements set forth in 35 U.S.C. §112, first paragraph (See, *e.g.*, *New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290 at 1296, 63 U.S.P.Q2d 1843 (Fed. Cir. 2002); *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 at 979, 63 U.S.P.Q.2d 1609 (Fed. Cir. 2002)). With respect to the presently claimed methods, this requirement is met for each of the parent cases. Accordingly, the present claims are entitled to the benefit of the complete priority claim listed on page 1 of the specification, which includes priority to U.S. Patent Application No. 09/925,284 (filed August 9, 2001), U.S. Patent Application No. 09/586,704 (filed June 5, 2000), PCT/US96/01383 (January 31, 1996) and U.S. Patent Application No. 08/381,528 (filed January 31, 1995).

Notwithstanding, even if the present claims are only entitled to the benefit of parent applications U.S. Patent Application No. 09/586,704 (filed June 5, 2000) and/or U.S. Patent Application No. 09/925,284 (filed August 9, 2001), Bonifaz *et al.* is still not available as a prior art reference against the present application.

In particular, the specification of parent application, U.S. Patent Application No. 09/586,704 (filed June 5, 2000), teaches the targeting of antigens to DEC-205 for immune modulation, *e.g.* stimulation of T cell immunity (page 45, lines 22-30). U.S. Patent Application No. 09/586,704 also teaches that dendritic cells can be activated (*e.g.*, maturation) using cytokines or lymphokines (page 46, lines 6-15). Therefore, each and every element of the pending claims is taught in the parent application.

The presently pending claims are also entitled to the benefit of priority to U.S. Patent Application No. 09/925,284 (filed August 9, 2001). The specification of U.S. Patent Application No. 09/925,284 is focused on the enhancement of antigen deliver to antigen-presenting cells and the manipulation of the immune response resulting therefrom (see page 3 (lines 16-18). Accordingly, exemplary support for the present claims can be found in U.S. Patent Application No. 09/925,284 at page 4 (lines 1-21); page 5 (lines 6-16); page 6 (lines 4-22); page 7 (lines 1-23); page 8, line 13 through page 9, line 5; page 9 (lines 10-16); (page 10,

lines 2-23); page 11, line 18 through page 12, line 3; page 13, line 11 through page 14, line 7; page 15, line 4 through page 27, line 7; page 24, line 7 through page 17, line 20; page 32, line 7 through page 44, line 20 and original claims 1-5 and 12. U.S. Patent Application No. 09/925,284 further teaches dendritic cell maturation techniques, including particular maturation factors (see, for example, page 4 (lines 15-21); page 5 (lines 10-16); page 7 (lines 12-23); page 10 (lines 19-23); page 14 (lines 1-7); page 15, line 21 through page 16, line 12; and page 24, line 7 through page 25, line 18).

Accordingly, based at least on the foregoing, the present application is at least entitled to the benefit of priority applications U.S. Patent Application No. 09/925,284 (filed August 9, 2001) and U.S. Patent Application No. 09/586,704 (filed June 5, 2000) and, therefore, Bonifaz *et al.* is not available as a prior art reference against the present application.

Rejection of Claims 1, 3-12, 14-28 and 55-56 Under 35 U.S.C. § 103(a)

Claims 1, 3-12, 14-28, 46 and 55-56 are rejected under 35 U.S.C. § 103(a) as being obvious over Bonifaz *et al.* in view of Germeraad *et al.* (US 2005/0037001).

Applicants respectfully traverse this rejection. As discussed above, the instant application claims and is entitled to priority to at least U.S. Patent Application No. 09/925,284 (filed August 9, 2001) and U.S. Patent Application No. 09/586,704 (filed June 5, 2000). Bonifaz *et al.* has an effective prior art date of December 16, 2002 and Germeraad *et al.* has an effective prior art date of February 2005. Thus, these references are not available as prior art against the present application. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

CONCLUSION

In view of the above amendments and remarks set forth above, it is respectfully submitted that this application is in condition for allowance. If there are any remaining issues or the Examiner believes that a telephone conversation with Applicants' Attorney could be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

Dated: January 9, 2009

Respectfully submitted,

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